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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/080,390	02/25/2002	Marc S. Hermelin	24016-A	9541

7590 01/22/2004

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EXAMINER	
LEVY, NEIL S	

ART UNIT	PAPER NUMBER
1616	

DATE MAILED: 01/22/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	10/080,390	HERMELIN ET AL.	
	Examin r	Art Unit	
	Neil Levy	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 38-68 is/are pending in the application.

4a) Of the above claim(s) 41-65 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 38-39, 66, 68 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 38-68 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 61-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 6.

Claims 38-60, 66-68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hsiao et al 4, 863, 743 in view of Myers et al 5,567,439 and Paradissis –4,764,375.

The rejection of record is maintained; see below. The instant claims are silent as to the Flavoring and taste masking agents, animal, particles, and extended release coating. Hsiao can be construed as meeting them, with the sugar, flavorant and taste masking agent, used in coated prior art tablets (col.7, last paragraph, top, and col. (8), if flavor is deemed a parameter of concern. In all other respects, Hsiao provides coated Kcl (Example 1) granules, with microcrystalline cellulose and crospovidone, PEG, as tablets, Example 2, adds magnesium stearate; similar to applicants Na-stearyl fumerate of Example 1; the tablets are the instant formulations of 20m Eq of Kcl. However 68%-86% Kcl is shown (column 7). Disintegration occurs within 5 minutes (column 5, lines 19-24) with sustained release leading to 90% Kcl released after 6 hours (Tables I, II).

The components providing for the dispersing and releases periods as instantly claimed are thus shown by Hsiao.

Administration as a liquid was seen as placing in water, or on an aqueous food, which is then administered to those having swallowing difficulties (col.5) line 65-line 7,

col.6). Stirring and Mixing if desired, is known-it was used in preparation (Example 2) thus would be within the purview of one to perform, if the desired dissolution period was shorter than produced by simply placing in water. This is the instant invention, absent clear showing of a colorant and flavorant. Paradissis is evidence it was well know at the time of the instant invention, to add colorants and flavorants even to taste-masked coated actives (col.2), including Kcl (claim 7), for particle dispersion in liquids. Further, multi substance preparations are also known (col.2, lines 35, 360.

Myers discloses examples of Flavorants (col.9, top through line 7, col. 10, and colorants (col. 10, lines 28-33), useful in drug tablet (col.7, lines 47-49) compositions.

It would have been obvious to a person of ordinary skill in the art at the time invention was made, desiring to utilize Hsiao's Kcl tablet in a form to provide enhanced palatability, dispensability and sustained release, as taught by Paradissis and exemplified by Myers.

All the critical elements of the instant are disclosed. The amounts, dosage regiments and mixing times are result effective parameters chosen to obtain the desired effects. It would be obvious to vary the ingredients to optimize the effect desired, depending upon the intended active agent, concern for side effects, species, age, sex, dosage, minimization of number of applications, patient acceptance for example.

The instant invention provides well-known old art recognized effects, applied by well known art-recognized methods to achieve the desired effects.

Applicant has not provided any objective evidence of criticality, nonobvious or unexpected results that administration methods with the particular ingredients' or

dispersion times provides any greater or different level of prior art expectation as claimed, and the use of ingredient for the functionality for which they are known to be used is not basis for patentability.

Applicant's arguments filed 10/23/03 have been fully considered but they are not persuasive. Applicant argues.

Hsiao teaches tablets which are sweetened. Flavorings and tastemasking are not taught. Further, Hsiao teaches, in Table I, that the controlled release is such that at least 91% of the active agent is released within 6 hours. As such, the tablets of Hsiao would result in a tablet, which was not as palatable as the one utilized in the present methods and which releases the active over a shorter period of time.

The secondary references do not remedy these deficiencies. Myers teaches tastemasking via an effervescent agent, which is outside the scope of the present invention. The present invention specifically avoids effervescent technologies.

Paradissis is not concerned with the overall design of a method to enhance patient compliance but rather a specific form of tastemasking of hydrophilic active agents.

Examiner finds "sweetners" absent specification of flavoring agent, meets this criteria, and also meets the new taste masking, also not specified, criteria. As to lacking palatability in comparison, we see no such claim to this condition, while the shorter period of time is still within the instant invention as it is claimed, agreed, the secondary references teach effervescence, but there is no proscription to one of ordinary skill in the art of administering therapeutics to a patient, to look at only selected references

directed at improving patient compliance. Note that the method as claimed is directed to animal oral dosing; patient compliance is not readily seen, as self dosing, or as selecting, ordering labeling, appropriate dosage, but rather patient acceptance upon human intervention, consisting of human administering the dosage. As to myers, myers is directed to controlled release systems (col.1, lines 12-14) col.4, lines 6-20) which includes instant and/or delayed or sustained release. The example is not to effervescent tablets. Neither does Paradissis require effervescence.

We fail to discern any distinction between the instant claimed invention and what one of ordinary skill in the art would provide, with the background, as represented by the cited references, of the means of enhancing acceptability by an animal of a therapeutic composition.

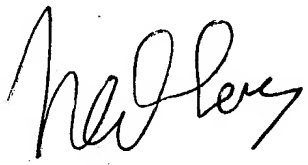
THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Levy whose telephone number is 571-272-0619. The examiner can normally be reached on Tuesday to Friday from 7:00a.m-5:30p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached on 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 308-4556 and (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1235.



Levy/tgd

January 14, 2004

NEIL S. LEVY
PRIMARY EXAMINER